GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

UNSTARRED QUESTION NO:1116
ANSWERED ON:22.11.2016
Drug Literature
Reddy Shri Konda Vishweshwar

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether it is mandatory for a drug manufacturer to provide drug literature along with their products and if so, the details thereof;

(b) whether the Government is aware of the fact that drug manufacturers have stopped providing drug literature along with their products and if so, the details thereof; and

(c) the action taken by the Government in this regard?:

Answer

MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS; MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH L. MANDAVIYA)

(a): Yes, Madam. As per Schedule Y of Drugs and Cosmetics Act, 1940 and Rules, 1945, manufacturer of new drug is required to submit product literature as a part of new drug application for marketing. The drafts of label and carton texts should comply with the provisions of Rules, 96 and 97.
(b): No incidence of not providing product literature with their product has been reported to Central Drugs Standard Control Organization (CDSCO).

(c): In view of reply to (b) above, does not arise.

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